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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,258	12/08/2000	Friedel Frauendorfer	H01.2-9587	7047

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 05/19/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,258

Applicant(s)

FRAUENDORFER, FRIEDEL

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination received on February 26, 2003 is acknowledged. Claims 1-11 are pending are included in the prosecution of this application.

Information Disclosure Statement

EP 0240581 cited in the Information Disclosure Statement is not considered since it is not translated nor does it contain an English abstract.

Response to Arguments

Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6-9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cade et al (WO 97/04755) in view of XP-002143507 or vice-versa.

XP teaches a gelatin capsule containing perilla oil, polyglycerol fatty acid ester, and monoglycerol fatty acid ester. One capsule contains 150mg of alpha-linolenic acid. The reference discloses that fats and oils that contain omega-3-polyenoic fatty acid and perilla, treat inflammatory bowel disease. Fats and oils containing preferably contain alpha-linolenic acid, eicosapentaenoic acid, or docosahexaenoic acid. See abstract.

XP does not specify the composition of the gelatin composition.

Cade et al teach hard gelatin with reduced water transport or water vapor permeation by either laminating a polymer layer onto the gelatin shell or adding an additive to the gelatin formulation. Additives such as xylose, which are added to the gelatin solution, reduce water permeability and hygroscopicity (pg. 7). Cade discloses that capsules with low permeability to water vapor reduce sensitivity to storage conditions and improves the protection of the compositions contained within (pg. 1, first paragraph) since permeation by the environment may cause the composition within to agglomerate or degrade chemically (pg. 2, fourth paragraph). Furthermore, the rupture or dissolving time of the capsule decreases with the increasing amount of additive (page 6). Rupture times are taught in Table 9. Lastly the capsule can be used as a container for nutrients, medicaments, etc. (page 10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Cade et al XP-002143507. One would be

Art Unit: 1616

motivated to harden a gelatin capsule with xylose since Cade et al teaches this reduces permeability by the environment that chemically degrades the contents of the capsules. Alternatively, one would be motivated to include fatty acids into the gelatin capsule of Cade et al to treat inflammatory bowel disease. It is the examiner's position that chemical degradation of the fill would read on the peroxidation of fatty acids since one mechanism for the deterioration of polyunsaturated fatty acids is oxidation in the presence of oxygen. Furthermore since Cade et al teach the use of sugar additives to prevent permeation of the environment into the capsule, it is implicit if the capsule prevents the presence of oxygen, the fatty acids will not undergo oxidation. In regards to the limitation "to an extent sufficient to inhibit peroxidation", it is the examiner's position that Cade's amount of xylose reads upon this broad limitation since the applicant has not provide any specific amount of xylose to demonstrate that Cade does not meet this limitation and since it is the inventive step of Cade to prevent the degradation of the contents inside the capsule.

Claims 1-7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yajima (4,525,306) in view of Cade et al (WO 97/04755).

Yajima teaches the prevention of oxidation of oils and fats and soft capsules containing the oils. The reference disclose that the prevention of the oxidation of oils and fats is accomplished by physical means such as keeping oils and fats away from oxygen and storing them at low temperatures, and adding antioxidants. See column 1, lines 5-20. Yajima teaches that although it is desirable from a nutritional point to ingest these fats and oils, fats and oils increase in their vulnerability to oxidation as the

Art Unit: 1616

constituent fatty acids increase in the degree of in saturation. It is taught that fish oil contains high contents of eicosapentaenoic acid and unsaturated fatty acids and is effective for the prevention of thrombi. See column 2, lines 14-35.

Yajima does not specify the gelatin capsule composition.

Cade et al teach hard gelatin with reduced water transport or water vapor permeation by either laminating a polymer layer onto the gelatin shell or adding an additive to the gelatin formulation. Additives such as xylose, which are added to the gelatin solution, reduce water permeability and hygroscopicity (pg. 7). Cade discloses that capsules with low permeability to water vapor reduce sensitivity to storage conditions and improves the protection of the compositions contained within (pg. 1, first paragraph) since permeation by the environment may cause the composition within to agglomerate or degrade chemically (pg. 2, fourth paragraph). Furthermore, the rupture or dissolving time of the capsule decreases with the increasing amount of additive (page 6). Rupture times are taught in Table 9. Lastly the capsule can be used as a container for nutrients, medicaments, etc. (page 10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Cade et al Yajima and incorporate xylose into the gelatin capsule. One would be motivated to do so since Cade et al teaches this reduces permeability by the environment that chemically degrades the contents of the capsules and Yajima teaches the increased susceptibility of unsaturated fatty acids to deterioration via oxidation in the presence of oxygen. Alternatively, one would be motivated to include fatty acids into the gelatin capsule of Cade et al to prevent thrombi

Art Unit: 1616

and for their nutritional value. It is the examiner's position that chemical degradation of the fill would read on the peroxidation of fatty acids since one mechanism for the deterioration of polyunsaturated fatty acids is oxidation in the presence of oxygen. In regards to the limitation "to an extent sufficient to inhibit peroxidation", it is the examiner's position that Cade's amount of xylose reads upon this broad limitation since the applicant has not provide any specific amount of xylose to demonstrate that Cade does not meet this limitation and since it is the inventive step of Cade to prevent the degradation of the contents inside the capsule.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Application/Control Number: 09/719,258

Page 7

Art Unit: 1616

SSG


May 14, 2003


MICHAEL G. HARTLEY
PRIMARY EXAMINER